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22 COUNSYL, INC.

23
24 IN THE UNITED STATES DISTRICT COURT
25 FOR THE NORTHERN DISTRICT OF CALIFORNIA

26 COUNSYL, INC.,

27 Plaintiff,

28 v.

MYRIAD GENETICS, INC.,

Defendant.

Case No.

**COMPLAINT FOR DECLATORY
JUDGMENT**

JURY TRIAL DEMANDED

1 Plaintiff Counsyl, Inc. ("Counsyl"), for its Complaint against Defendant Myriad Genetics, Inc.
2 ("Myriad") alleges as follows:

3 **NATURE OF THE ACTION**

4 1. This is an action brought by Counsyl to obtain declaratory judgment that Myriad has no
5 rights against Counsyl regarding the following patents pursuant to Federal Rules of Civil Procedure 57
6 and 28 U.S.C. § 2201:

7 a. U.S. Patent No. 5,709,999, entitled "LINKED BREAST AND OVARIAN
8 CANCER SUSCEPTIBILITY GENE," issued on January 20, 1998 ("the '999 patent"). A true and
9 correct copy of the '999 patent is attached as Exhibit 1.

10 b. U.S. Patent No. 5,747,282, entitled "17Q-LINKED BREAST AND OVARIAN
11 CANCER SUSCEPTIBILITY GENE," issued on May 5, 1998 ("the '282 patent"). A true and correct
12 copy of the '282 patent is attached as Exhibit 2.

13 c. U.S. Patent No. 5,753,441, entitled "17Q-LINKED BREAST AND OVARIAN
14 CANCER SUSCEPTIBILITY GENE," issued on May 19, 1998 ("the '441 patent"). A true and correct
15 copy of the '441 patent is attached as Exhibit 3.

16 d. U.S. Patent No. 6,951,721, entitled "METHOD FOR DETERMINING THE
17 HAPLOTYPE OF A HUMAN BRCA1 GENE," issued on October 4, 2005 ("the '721 patent"). A true
18 and correct copy of the '721 patent is attached as Exhibit 4.

19 e. U.S. Patent No. 7,250,497, entitled "LARGE DELETIONS IN HUMAN BRCA1
20 GENE AND USE THEREOF," issued on July 31, 2007 ("the '497 patent"). A true and correct copy of
21 the '497 patent is attached as Exhibit 5.

22 f. U.S. Patent No. 5,837,492, entitled "CHROMOSOME 13-LINKED BREAST
23 CANCER SUSCEPTIBILITY GENE," issued on November 17, 1998 ("the '492 patent"). A true and
24 correct copy of the '492 patent is attached as Exhibit 6.

25 g. U.S. Patent No. 6,033,857, entitled "CHROMOSOME 13-LINKED BREAST
26 CANCER SUSCEPTIBILITY GENE," issued on March 7, 2000 ("the '857 patent"). A true and correct
27 copy of the '857 patent is attached as Exhibit 7.

28 ///

1 8. Myriad has asserted that it owns and/or has the sole right to enforce the '999, '282, '441,
2 '721, '497, '492, '857, and '379 patents.

3 9. Myriad itself claims that, by offering its allegedly patented testing services to breast
4 and/or ovarian cancer patients and their family members, and by excluding any potential competitors
5 from being able to offer women any alternatives to the Myriad test, Myriad has created an extensive
6 database of genetic variants of *BRCA1* and *BRCA2*. Since 2005, however, Myriad has kept the vital
7 public health information in this database a secret, and has refused to share it with healthcare workers
8 and the public. Thus, Myriad has effectively hindered the medical community from being able to use
9 patient data to further medical research and impeded the ability of clinicians to interpret genomic data.

10 10. Myriad has asserted that any company that makes, uses, sells, or offers to sell genetic tests
11 and related services using the *BRCA1* and/or *BRCA2* genes, such as the sequencing and analysis of
12 *BRCA1* and/or *BRCA2* genes, faces the risk of suit for infringement of one or more claims of the '999,
13 '282, '441, '721, '497, '492, '857, and '379 patents.

14 11. Certain claims of the '999, '282, '441, '492, and '857 patents have been the subject of a
15 prior patent litigation, which culminated in the review of the validity of those claims by the Supreme
16 Court. In its decision on June 13, 2013, *Association for Molecular Pathology v. Myriad Genetics*, 133 S.
17 Ct. 2107, 2013 WL 2631062, the Supreme Court held that at least claims 1 and 5 of the '282 patent and
18 claims 1 and 6 of the '492 patent directed to isolated human *BRCA1* and *BRCA2* genes are invalid for
19 lack of patentable subject matter under 35 U.S.C. § 101. Moreover, in the proceedings leading up to the
20 Supreme Court decision, the Federal Circuit had reviewed claim 1 of the '999 patent, claim 1 of the '441
21 patent, claims 1 and 2 of the '857 patent directed to methods of using human *BRCA1* and *BRCA2* genes
22 to detect alterations or to screen for alterations and held that those claims also are invalid for lack of
23 patentable subject matter under 35 U.S.C. § 101. *Ass'n for Molecular Pathology v. U.S. Patent &*
24 *Trademark Office*, 689 F.3d 1303, 1329 (Fed. Cir. 2012). That decision was not appealed by either party.

25 12. Notwithstanding these rulings, Myriad has stated that it still intends to aggressively and
26 vigorously enforce the '999, '282, '441, '721, '497, '492, '857, and '379 patents against any entity that
27 makes, uses, sells, or offers to sell genetic tests and related services using the *BRCA1* and/or *BRCA2*
28 genes, such as the sequencing and analysis of *BRCA1* and/or *BRCA2* genes.

1 13. Numerous clinicians and entities performing research on *BRCA1* and/or *BRCA2* genes
2 have stated that Myriad has sent them cease and desist letters, effectively prohibiting routine screening of
3 *BRCA1* and/or *BRCA2* genes for research or clinical practice without a license to the '999, '282, '441,
4 '721, '497, '492, '857, and '379 patents.

5 14. After the Supreme Court decision, two other entities, Ambry Genetics Corp. and Gene by
6 Gene Ltd., publicly stated on June 13, 2013, that they would begin offering their respective genetic tests
7 and related services that included sequencing and analysis of the *BRCA1* and/or *BRCA2* genes. In
8 response, Myriad sued Ambry and Gene by Gene on July 9, 2013, and July 10, 2013, respectively, for
9 infringement of certain claims of the '999, '282, '441, '721, '497, '492, '857, and '379 patents. Those
10 suits have been consolidated and are pending in the District of Utah, Central Division. *See Univ. of Utah*
11 *Research Found. v. Ambry Genetics, Inc.*, No. 2:13-cv-000640 (D. Utah filed July 9, 2013) and *Univ. of*
12 *Utah Research Found. v. Gene by Gene*, No. 2:13-cv-000640 (D. Utah filed July 10, 2013).

13 15. Myriad's conduct, including Myriad's litigation history, puts at risk Counsyl's legal rights
14 and ability to market its genetic tests and related services related to sequencing and analysis of *BRCA1*
15 and *BRCA2* genes.

16 16. Counsyl has made a substantial research and development investment in improving
17 genetic tests and providing more access at lower cost to related services connected with sequencing and
18 analysis of *BRCA1* and *BRCA2* genes. Accordingly, Counsyl seeks and is lawfully entitled to a
19 declaratory judgment that at least one of the following claims is invalid and/or not infringed: claim 6 of
20 the '999 patent, claims 5 and 6 of the '282 patent, claims 8, 23, 33 of the '441 patent, claim 5 of the '721
21 patent, claims 1-20 of the '497 patent, claims 5, 9, 29, 30 of the '492 patent, claim 4 of the '857 patent,
22 and claims 1-25, 40-42 of the '379 patent.

23 17. There is a definite, concrete, real and substantial controversy between Counsyl and
24 Myriad of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of at least
25 one of claim 6 of the '999 patent, claims 5 and 6 of the '282 patent, claims 8, 23, 33 of the '441 patent,
26 claim 5 of the '721 patent, claims 1-20 of the '497 patent, claims 5, 9, 29, 30 of the '492 patent, claim 4
27 of the '857 patent, and claims 1-25, 40-42 of the '379 patent. A declaration of rights between the parties
28 is both appropriate and necessary to establish that Counsyl does not infringe any valid claim of the '999,

1 '282, '441, '721, '497, '492, '857, and '379 patents.

2 JURISDICTION AND VENUE

3 18. This lawsuit is a civil action arising under the patent laws of the United States, 35 U.S.C.
4 § 100, *et seq.*, and the Declaratory Judgment Act, 35 U.S.C. § 2201. Accordingly, this Court has subject
5 matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6 19. This Court has personal jurisdiction over Myriad, by virtue of, *inter alia*, it having
7 conducted business in California, having availed itself of the rights and benefits of California law, and
8 having engaged in substantial and continuing contacts with California.

9 20. On information and belief, Myriad conducts substantial business in this judicial district
10 and regularly solicits business from, does business with, and derives value from goods and services
11 provided to customers in this judicial district. For example, Myriad employs a significant sales and
12 marketing force in this District, markets its tests to thousands of residents within this District, generates
13 significant revenues from this District, and has made significant investments in this District, including a
14 \$25 million strategic investment in Crescendo Bioscience based in South San Francisco, California, in
15 2011. *See, e.g., Myriad Genetics Makes Strategic Debt Investment With Exclusive Option to Acquire*
16 *Crescendo Bioscience*, Myriad Investor Relations Press Releases (Sept. 8, 2011),
17 <http://investor.myriad.com/releasedetail.cfm?ReleaseID=604160>.

18 21. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

19 COUNT I

20 DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '999 PATENT

21 22. Counsyl incorporates by reference the preceding averments set forth in paragraphs 1-21.

22 23. An actual controversy exists between Counsyl and Myriad with respect to Counsyl's
23 noninfringement of claim 6 of the '999 patent.

24 24. Counsyl has not directly or indirectly infringed and is not directly or indirectly infringing
25 claim 6 of the '999 patent as defined by 35 U.S.C. § 271.

26 25. Counsyl hereby seeks a declaration that the manufacture, use, offer for sale, or sale of its
27 genetic sequencing and analysis of the *BRCA1* gene does not directly or indirectly infringe claim 6 of the
28 '999 patent.

COUNT II

DECLARATORY JUDGMENT OF INVALIDITY OF THE '999 PATENT

26. Counsyl incorporates by reference the preceding averments set forth in paragraphs 1-25.

27. An actual controversy exists between Counsyl and Myriad with respect to the invalidity of claim 6 of the '999 patent.

28. Claim 6 of the '999 patent fails to meet one or more of the statutory requirements and/or conditions for patentability under the patent laws of the United States, including but not limited to 35 U.S.C. §§ 101-103, 112, *et seq.*, and/or under the judicially created doctrine of obviousness-type double patenting.

29. Counsyl hereby seeks a declaration that claim 6 of the '999 patent is invalid.

COUNT III

DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '282 PATENT

30. Counsyl incorporates by reference the preceding averments set forth in paragraphs 1-29.

31. An actual controversy exists between Counsyl and Myriad with respect to Counsyl's noninfringement of at least one of claims 5 and/or 6 of the '282 patent.

32. Counsyl has not directly or indirectly infringed and is not directly or indirectly infringing claims 5 and/or 6 of the '282 patent as defined by 35 U.S.C. § 271.

33. Counsyl hereby seeks a declaration that the manufacture, use, offer for sale, or sale of its genetic sequencing and analysis of the *BRCA1* gene does not directly or indirectly infringe claims 5 and/or 6 of the '282 patent.

COUNT IV

DECLARATORY JUDGMENT OF INVALIDITY OF THE '282 PATENT

34. Counsyl incorporates by reference the preceding averments set forth in paragraphs 1-33.

35. An actual controversy exists between Counsyl and Myriad with respect to the invalidity of at least one of claims 5 and/or 6 of the '282 patent.

36. Claims 5 and/or 6 of the '282 patent fail to meet one or more of the statutory requirements and/or conditions for patentability under the patent laws of the United States, including but not limited to 35 U.S.C. §§ 101-103, 112, *et seq.*, and/or under the judicially created doctrine of obviousness-type

1 double patenting.

2 37. Counsyl hereby seeks a declaration that claims 5 and/or 6 of the '282 patent are invalid.

3 **COUNT V**

4 **DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '441 PATENT**

5 38. Counsyl incorporates by reference the preceding averments set forth in paragraphs 1-37.

6 39. An actual controversy exists between Counsyl and Myriad with respect to Counsyl's
7 noninfringement of at least one of claims 8, 23, and/or 33 of the '441 patent.

8 40. Counsyl has not directly or indirectly infringed and is not directly or indirectly infringing
9 claims 8, 23, and/or 33 of the '441 patent as defined by 35 U.S.C. § 271.

10 41. Counsyl hereby seeks a declaration that the manufacture, use, offer for sale, or sale of its
11 genetic sequencing and analysis of the *BRCA1* gene does not directly or indirectly infringe claims 8, 23,
12 and/or 33 of the '441 patent.

13 **COUNT VI**

14 **DECLARATORY JUDGMENT OF INVALIDITY OF THE '441 PATENT**

15 42. Counsyl incorporates by reference the preceding averments set forth in paragraphs 1-41.

16 43. An actual controversy exists between Counsyl and Myriad with respect to the invalidity of
17 at least one of claims 8, 23, and/or 33 of the '441 patent.

18 44. Claims 8, 23, and/or 33 of the '441 patent fail to meet one or more of the statutory
19 requirements and/or conditions for patentability under the patent laws of the United States, including but
20 not limited to 35 U.S.C. §§ 101-103, 112, *et seq.*, and/or under the judicially created doctrine of
21 obviousness-type double patenting.

22 45. Counsyl hereby seeks a declaration that claims 8, 23, and/or 33 of the '441 patent are
23 invalid.

24 **COUNT VII**

25 **DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '721 PATENT**

26 46. Counsyl incorporates by reference the preceding averments set forth in paragraphs 1-45.

27 47. An actual controversy exists between Counsyl and Myriad with respect to Counsyl's
28 noninfringement of claim 5 of the '721 patent.

1 48. Counsyl has not directly or indirectly infringed and is not directly or indirectly infringing
2 claim 5 of the '721 patent as defined by 35 U.S.C. § 271.

3 49. Counsyl hereby seeks a declaration that the manufacture, use, offer for sale, or sale of its
4 genetic sequencing and analysis of the *BRCA1* gene does not directly or indirectly infringe claim 5 of the
5 '721 patent.

6 **COUNT VIII**

7 **DECLARATORY JUDGMENT OF INVALIDITY OF THE '721 PATENT**

8 50. Counsyl incorporates by reference the preceding averments set forth in paragraphs 1-49.

9 51. An actual controversy exists between Counsyl and Myriad with respect to the invalidity of
10 claim 5 of the '721 patent.

11 52. Claim 5 of the '721 patent fails to meet one or more of the statutory requirements and/or
12 conditions for patentability under the patent laws of the United States, including but not limited to 35
13 U.S.C. §§ 101-103, 112, *et seq.*, and/or under the judicially created doctrine of obviousness-type double
14 patenting.

15 53. Counsyl hereby seeks a declaration that claim 5 of the '721 patent is invalid.

16 **COUNT IX**

17 **DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '497 PATENT**

18 54. Counsyl incorporates by reference the preceding averments set forth in paragraphs 1-53.

19 55. An actual controversy exists between Counsyl and Myriad with respect to Counsyl's
20 noninfringement of at least one of claims 1-20 of the '497 patent.

21 56. Counsyl has not directly or indirectly infringed and is not directly or indirectly infringing
22 claims 1-20 of the '497 patent as defined by 35 U.S.C. § 271.

23 57. Counsyl hereby seeks a declaration that the manufacture, use, offer for sale, or sale of its
24 genetic sequencing and analysis of the *BRCA1* gene does not directly or indirectly infringe claims 1-20 of
25 the '497 patent.

26 **COUNT X**

27 **DECLARATORY JUDGMENT OF INVALIDITY OF THE '497 PATENT**

28 58. Counsyl incorporates by reference the preceding averments set forth in paragraphs 1-57.

59. An actual controversy exists between Counsyl and Myriad with respect to the invalidity of at least one of claims 1-20 of the '497 patent.

60. Claims 1-20 of the '497 patent fail to meet one or more of the statutory requirements and/or conditions for patentability under the patent laws of the United States, including but not limited to 35 U.S.C. §§ 101-103, 112, *et seq.*, and/or under the judicially created doctrine of obviousness-type double patenting.

61. Counsyl hereby seeks a declaration that claims 1-20 of the '497 patent are invalid.

COUNT XI

DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '492 PATENT

62. Counsyl incorporates by reference the preceding averments set forth in paragraphs 1-61.

63. An actual controversy exists between Counsyl and Myriad with respect to Counsyl's noninfringement of at least one of claims 5 and/or 9 of the '492 patent.

64. Counsyl has not directly or indirectly infringed and is not directly or indirectly infringing claims 5 and/or 9 of the '492 patent as defined by 35 U.S.C. § 271.

65. Counsyl hereby seeks a declaration that the manufacture, use, offer for sale, or sale of its genetic sequencing and analysis of the *BRCA2* gene does not directly or indirectly infringe claims 5 and/or 9 of the '492 patent.

COUNT XII

DECLARATORY JUDGMENT OF INVALIDITY OF THE '492 PATENT

66. Counsyl incorporates by reference the preceding averments set forth in paragraphs 1-65.

67. An actual controversy exists between Counsyl and Myriad with respect to the invalidity of at least one of claims 5 and/or 9 of the '492 patent.

68. Claims 5 and/or 9 of the '492 patent fail to meet one or more of the statutory requirements and/or conditions for patentability under the patent laws of the United States, including but not limited to 35 U.S.C. §§ 101-103, 112, *et seq.*, and/or under the judicially created doctrine of obviousness-type double patenting.

69. Counsyl hereby seeks a declaration that claims 5 and/or 9 of the '492 patent are invalid.

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COUNT XIII

DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '857 PATENT

70. Counsyl incorporates by reference the preceding averments set forth in paragraphs 1-69.

71. An actual controversy exists between Counsyl and Myriad with respect to Counsyl's noninfringement of claim 4 of the '857 patent.

72. Counsyl has not directly or indirectly infringed and is not directly or indirectly infringing claim 4 of the '857 patent as defined by 35 U.S.C. § 271.

73. Counsyl hereby seeks a declaration that the manufacture, use, offer for sale, or sale of its genetic sequencing and analysis of the *BRCA2* gene does not directly or indirectly infringe claim 4 of the '857 patent.

COUNT XIV

DECLARATORY JUDGMENT OF INVALIDITY OF THE '857 PATENT

74. Counsyl incorporates by reference the preceding averments set forth in paragraphs 1-73.

75. An actual controversy exists between Counsyl and Myriad with respect to the invalidity of claim 4 of the '857 patent.

76. Claim 4 of the '857 patent fails to meet one or more of the statutory requirements and/or conditions for patentability under the patent laws of the United States, including but not limited to 35 U.S.C. §§ 101-103, 112, *et seq.*, and/or under the judicially created doctrine of obviousness-type double patenting.

77. Counsyl hereby seeks a declaration that claim 4 of the '857 patent is invalid.

COUNT XV

DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '379 PATENT

78. Counsyl incorporates by reference the preceding averments set forth in paragraphs 1-77.

79. An actual controversy exists between Counsyl and Myriad with respect to Counsyl's noninfringement of at least one of claims 1-20, 24, 25, 40 and/or 41 of the '379 patent.

80. Counsyl has not directly or indirectly infringed and is not directly or indirectly infringing claims 1-20, 24, 25, 40 and/or 41 of the '379 patent as defined by 35 U.S.C. § 271.

81. Counsyl hereby seeks a declaration that the manufacture, use, offer for sale, or sale of its

1 genetic sequencing and analysis of the *BRCA2* gene does not directly or indirectly infringe claims 1-20,
2 24, 25, 40 and/or 41 of the '379 patent.

3 **COUNT XVI**

4 **DECLARATORY JUDGMENT OF INVALIDITY OF THE '379 PATENT**

5 82. Counsyl incorporates by reference the preceding averments set forth in paragraphs 1-81.

6 83. An actual controversy exists between Counsyl and Myriad with respect to the invalidity of
7 at least one of claims 1-20, 24, 25, 40 and/or 41 of the '379 patent.

8 84. Claims 1-20, 24, 25, 40 and/or 41 of the '379 patent fail to meet one or more of the
9 statutory requirements and/or conditions for patentability under the patent laws of the United States,
10 including but not limited to 35 U.S.C. §§ 101-103, 112, *et seq.*, and/or under the judicially created
11 doctrine of obviousness-type double patenting.

12 85. Counsyl hereby seeks a declaration that claims 1-20, 24, 25, 40 and/or 41 of the '379
13 patent are invalid.

14 **PRAYER FOR RELIEF**

15 WHEREFORE, Counsyl respectfully requests that:

16 A. Judgment be entered declaring that Counsyl has not infringed, induced infringement of, or
17 contributed to the infringement of and is not infringing, inducing the infringement of, or contributing to
18 the infringement of any one of the following claims: claim 6 of the '999 patent, claims 5, 6, of the '282
19 patent, claims 8, 23, 33 of the '441 patent, claim 5 of the '721 patent, claims 1-20 of the '497 patent,
20 claims 5, 9 of the '492 patent, claim 4 of the '857 patent, and/or claims 1-20, 24, 25, 40 and/or 41 of the
21 '379 patent;

22 B. Judgment be entered declaring that claim 6 of the '999 patent, claims 5, 6, of the '282
23 patent, claims 8, 23, 33 of the '441 patent, claim 5 of the '721 patent, claims 1-20 of the '497 patent,
24 claims 5, 9 of the '492 patent, claim 4 of the '857 patent, and/or claims 1-20, 24, 25, 40 and/or 41 of the
25 '379 patent are invalid;

26 C. Judgment be entered finding that this is an exceptional case entitling Counsyl to an award
27 of attorneys' fees for bringing and prosecuting this action, together with interest, and costs of the action
28 under 35 U.S.C. § 285; and

1 D. Such other and further relief as this Court may deem just and proper.

2 **JURY DEMAND**

3 Plaintiff hereby requests a trial by jury, pursuant to Federal Rule of Civil Procedure 38(b), on all
4 issues so triable.

5 Dated: September 20, 2013

DURIE TANGRI LLP

6
7 By: 

8 DARALYN J. DURIE
9 MARK A. LEMLEY

10 Attorneys for Plaintiff
11 COUNSYL, INC.
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